APPLICATION FOR UNITED STATES LETTERS PATENT

For

METHOD AND SYSTEM FOR INTEGRATING FEEDBACK LOOPS IN MEDICAL KNOWLEDGE DEVELOPMENT AND HEALTHCARE MANAGEMENT

Inventors:

Stephen J. Brown
Geoffrey J. Clapp

Prepared by:

BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
12400 Wilshire Boulevard
Los Angeles, CA 90025-1026
(408) 720-8300

Attorney's Docket No.: 6858P056

"Express Mail" mailing label number: EV 439337996 US
Date of Deposit: 04/07/2004
I hereby certify that I am causing this paper or fee to be deposited with the United States Postal Service "Express Mail Post Office to Addressee" service on the date indicated above and that this paper or fee has been addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Dawn R. Shaw
(Typed or printed name of person mailing paper or fee)

Dawn R. Shaw
(Signature of person mailing paper or fee)

4/7/04
(Date signed)

METHOD AND SYSTEM FOR INTEGRATING FEEDBACK LOOPS IN MEDICAL KNOWLEDGE DEVELOPMENT AND HEALTHCARE MANAGEMENT

Inventors:
Stephen J. Brown
Geoffrey J. Clapp

CLAIM OF PRIORITY

This application claims the priority of U.S. Provisional Application No. 60/461,105 filed April 7, 2003 and U.S. Provisional Application No. 60/461,526 filed April 8, 2003, both of which are incorporated herein by reference.

E-health technologies are enabling a shift in the paradigm of healthcare from a model overly devoted to episodic, crisis-driven care toward a model characterized by continuity, crisis prevention, citizen empowerment, and ubiquitous monitoring and management of health and lifestyle factors outside of the traditional patient encounter. This paradigm shift is generating new opportunities and demands to advance and disseminate medical knowledge toward truly individualized care, yet new tools are needed before such advances can be integrated into clinical practice and be made available to citizens. The need for new tools is particularly acute – and the opportunity particularly large – in chronic care, where the need for care is increasing due to the aging population while the supply of caregivers is declining.

This proposal research and develop of a comprehensive new methodology and tool set for medical knowledge management, dissemination, and individualization. The research and development activities include (1) development of an ontology and semantics engine for medical knowledge and patient information from diverse and heterogeneous sources in order to determine best practices and consensus standards of care on a continuous basis, (2) development of decision support and knowledge dissemination tools in order to generate timely, relevant, and individualized care plans and patient education, and (3) development of a continuous feedback methodology and system whereby data gathered from the citizen enables care providers to automatically individualize care plans and patient communications and medical researchers to continuously test and validate rules and associations that drive that individualization.

Additionally, tools will be developed to enable researchers to identify patient characteristics that correlate to disease progression and outcomes and study of disease based on far more detailed patient data, collected at far higher frequency, and on a larger scale than was previously possible. The vast new amounts and sources of data, particularly high frequency data from ubiquitous monitoring outside of the traditional encounter necessitates the development of a new generation of knowledge management tools that automate and integrate the collection, processing and dissemination of medical knowledge to a greater degree than has previously existed.

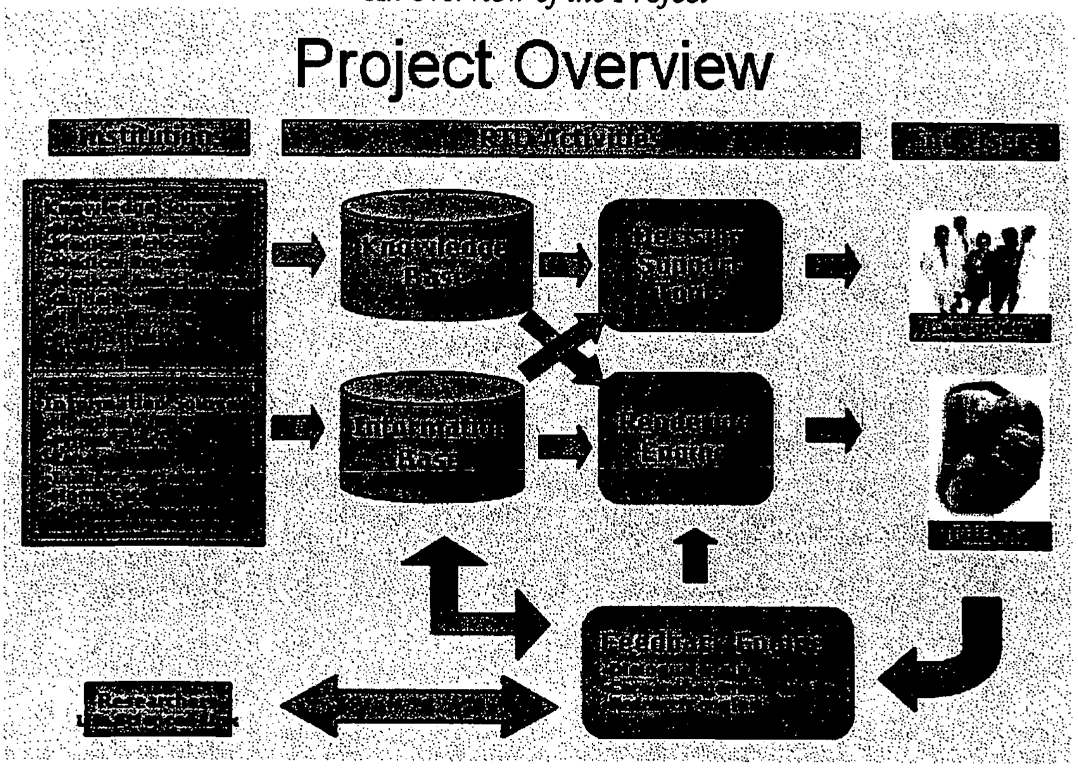
As these e-health care management tools are disseminated and introduced into clinical practice and medical research, it will become possible for care providers, patients, and researchers to better understand, predict, prevent, and manage disease. The overall goal is

to apply and generate medical knowledge in a continuous dynamic feedback process that leads to the lowest achievable risk and cost to society and the highest quality of care and quality of life for citizens.

II. Executive Summary

In view of the above, MedKnowledgeMent aims to provide the methodology and tools for implementing a comprehensive knowledge management strategy in the medical environment, with the capability to encompass, classify, process and deliver the necessary information at the appropriate time.

An overview of the Project



The proposed project will include-

<u>I.</u> <u>Information and Knowledge sources</u>-

Relationships will be established with sources of medical knowledge, including Universities, Medical Schools, Hospitals, Clinical Laboratories, Primary Care Units, Physicians, Care Managers, Medical Research Facilities, medical literature, and other sources of medical knowledge. There shall be co-ordination with these sources in order to develop the overall system.

<u>II.</u> <u>Knowledge Acquisition- Knowledge Base:</u>

An ontology will be developed for medical knowledge in order to specify how medical knowledge sources apply to specific disease conditions and patient

populations. In this ontology, each disease diagnosis will be associated with a set of representational terms covering aspects of care for the condition. Sub categorization under the aspect of care will include available treatments, and conditions upon which such treatments are used. Based on this ontology, a medical knowledge base will be developed from which it will be possible to search for and determine the consensus standards of care based on search criteria. An application program interface (API) and query language will be developed to this knowledge base so that other programs can use the knowledge base to run queries for specific needs in order to determine and derive consensus standards of care in a structured way that can be applied as a rule base a decision support system. For example, a care management program could seek information on the consensus standard of care for frequency of a particular lab test for a particular disease, as in HbA1c tests for a patient with Type II diabetes in a particular age group of patients. Because lab tests for particular diagnosis will be part of the ontology for classification of knowledge in relation to a disease, the methodology will allow such a query. Research and development needs to be done to create a generally applicable ontology and semantic network that will allow a scalable classification of knowledge across a wide range of disease conditions and populations. Interface to this subcomponent will be an API and query language. For this project, care plans will be developed for a range of conditions including Chronic Obstructive Pulmonary Disease, Congestive Heart Failure, Type II Diabetes Mellitus, End Stage Renal Disease/Transplant, and Depression.

<u>III.</u> <u>Information Acquisition- Information Base</u>:
An ontology and query language will be developed in order to extract data from existing clinical information systems including Electronic Health Records (EHR), Laboratory Databases, Medical Claims Databases, Genetic and Molecular Biology Databases in addition to patient self-reported data that is entered via the Internet and self-care devices. Based on this, an Information Base is generated and integrated in real-time.

Semantics Engine will have the capability to integrate patient information from multiple sources of External Data, including electronic health records, laboratory data, medical claims data, genetic and molecular biology data. Semantics Engine references the data available from the external sources, and integrates this data into the patient's Information Base through the use of an API. Data is classified in a standard manner to allow the extraction of necessary elements to compute risk factors for each of the health contexts in the 3-dimensional model of disease for every patient.

The Electronic Health Records (EHR) of a patient is referenced, and information is extracted by the usage of Natural Language Processing Algorithms. The typical information that would be extracted from an EHR includes

- Patient demographic variables, including name, age, sex, race, national ID number, contact information
- main diagnosis, co-morbid conditions,
- chief complaints, physical examination findings,

- family history,
- lifestyle related factors, such as a history of smoking , alcohol consumption, exercise
- frequency of visits to the healthcare facility,
- referrals to other health providers, including specialists, co-morbid conditions,
- diagnostic tests ordered, dates of ordering of these tests, and results of the diagnostic tests. Included here are the radiological, nuclear medicine investigations and functional tests such as exercise stress tests.
- prescribed medication, response to medication, development of side-effects, especially if the side-effects have necessitated withdrawal of the medication,
- history of admissions, special procedures (such as operations) undertaken, indications for the procedure

Laboratory Data includes data from a diagnostic laboratory- biochemical, pathology, and microbiology, immunological investigations. The data which is of primary concern to the system is the date, and type of test, and the test result. The test results may be used to schedule additional tests through the use of further protocols. For example, if a test value is reported as high, the Care Manager Program institutes an intervention, as indicated by the protocol, in addition to scheduling a follow up laboratory test to check the effectiveness of the protocol in patient care.

Medical Claims Data from the database of an insurer or public health subsidizing organization is extracted by the Semantics Engine and complements the data in the EHR. Medical Claims Data provides information on the dates and nature of procedures, tests and consultations that a patient undergoes. This information is further processed by protocols. For instance, the claims data for a diabetic patient may show that the recent most visit to an ophthalmologist to be 3 years previously, whereas the standard of care requires this to be every 2 years. Care Management Engine alerts the care manager to this fact, and a new consultation is scheduled. Semantic Engine correlates the medical claims data and EHR in order to prevent duplication of data.

Genetic and Molecular Diagnostics Database- Semantic Engine extracts a patient's genetic and molecular profile from a Genetics Database, and incorporates this information within Information Base. This is used by Care Management Engine to modify the treatment plan of an individual on the basis of his/her molecular and genetic profile. For example, patients with polymorphisms in genes for cytochrome oxidases exhibit a different degree of metabolism, and side effects of antidepressants and tests for cytochrome polymorphisms may be used to determine the best drug to be used in a given patient. Another interesting application is that this data may be used by the research engine to correlate subgroups of patients based on treatment response and disease outcomes (phenotypic variables) to genetic variations including SNP markers and molecular profiles. . Many chronic diseases such as diabetes, hypertension, cardiovascular disease, obesity, and mental health disorders are thought to have a genetic component.

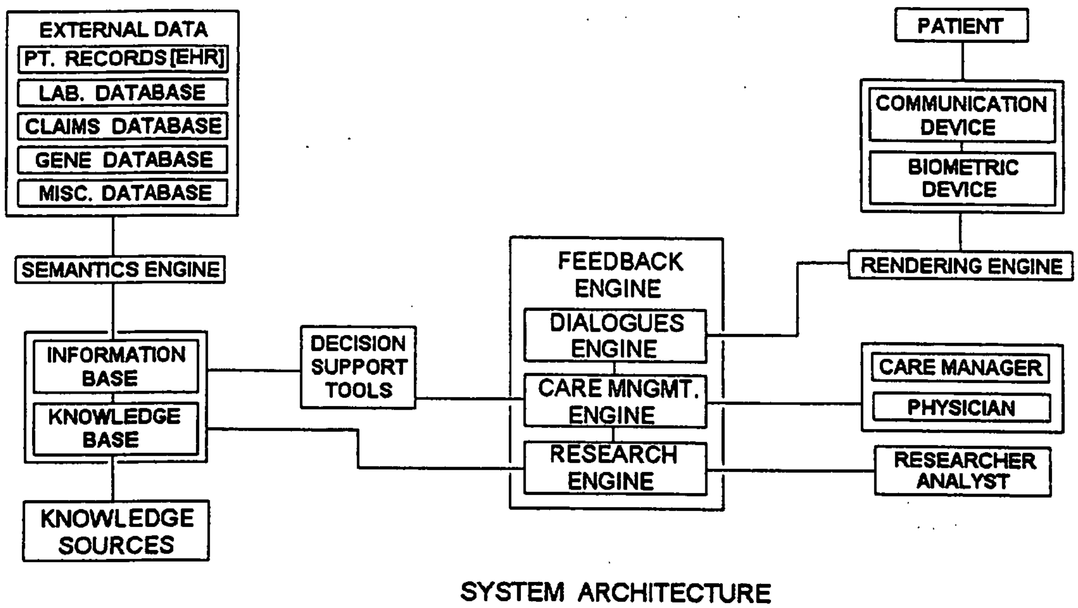
IV. Information and Knowledge Processing: Decision Support Tools-
Queries will be run on Information Base to correlate the extent to which provided care is consistent with the consensus standard of care- the Knowledge Base. Decision Support Tools (DSTs) will use the results of these queries to generate reports that identify potential gaps in patient care. These 'gaps' in care, the difference between hitherto provided care and the consensus standard care' is summarized, and presented to caregivers, i.e. physicians and care managers. For example, patients with diabetes are required by knowledge base to have an HbA1c test every three months. In cases where DSTs detects that the last such test has been performed more than this interval, a recommendation is given to check if the patient has had an unreported test. If this is the case, then the missing test results are entered into the information base. If not, then the test is performed. In the interest of patient safety and quality assurance, it is necessary that the physician or care manger screens the 'care gap' report and confirms that the gaps are not due to missing data.

V. Information and Knowledge Rendering: Rendering Engine-
Dialogues and health content is rendered for presentation, by a Rendering Engine that converts the data into a format which may be interpreted by different types of devices including Personal Computers connected to the Internet, interactive Television, Personal Digital Assistants, and remote health appliances, such as the Health Buddy TM appliance that are used by a patient to communicate with the system. Conversely, Rendering Engine converts patient replies to dialogs, and biometric measurements from different devices into the standard system format.

VI. Information and Knowledge Acquisition: Feedback Engine-
The Feedback Engine is of key importance in the knowledge management cycle. Feedback Engine will enable a regular and ongoing interaction between the patient and the care manager, physician and researcher, outside of the clinical encounter. Feedback Engine will interface with DSTs using Application Program Interfaces, to generate personalized recommended 'care plans' based on the patient's updated Information Base and disease Knowledge Base. Care plans will be forward looking and will recommend steps for monitoring and managing patients along a future timeline. The structure of the monitoring and management plan is based on the characteristics- symptoms, behavior (i.e. treatment compliance), knowledge and test results matched to medically relevant aspects of care. The plan will include monitoring, management and follow-up directly with the patient and reporting to the care manager. This is an intervention that would be implemented using eHealth technologies for frequent dialogues with the patient over a network. It will also include a customized health education plan. Caregivers, i.e. physicians and care managers decide, in consultation with the patient the future course of action, with regard to the recommended care plan. In the first iteration of the patient monitoring and management plan, the plan is based on the personalization of a pre-packaged care plan designed for the specific medical condition of the patient. Subsequent iterations will allow for progressively greater customization and individualization of plans to the information base. Feedback Engine will allow the system to correlate and analyze

data within Information Base and Knowledge Base and apply these analyses to make new discoveries and further the growth of medical science.

Feedback Engine will consist of three components-

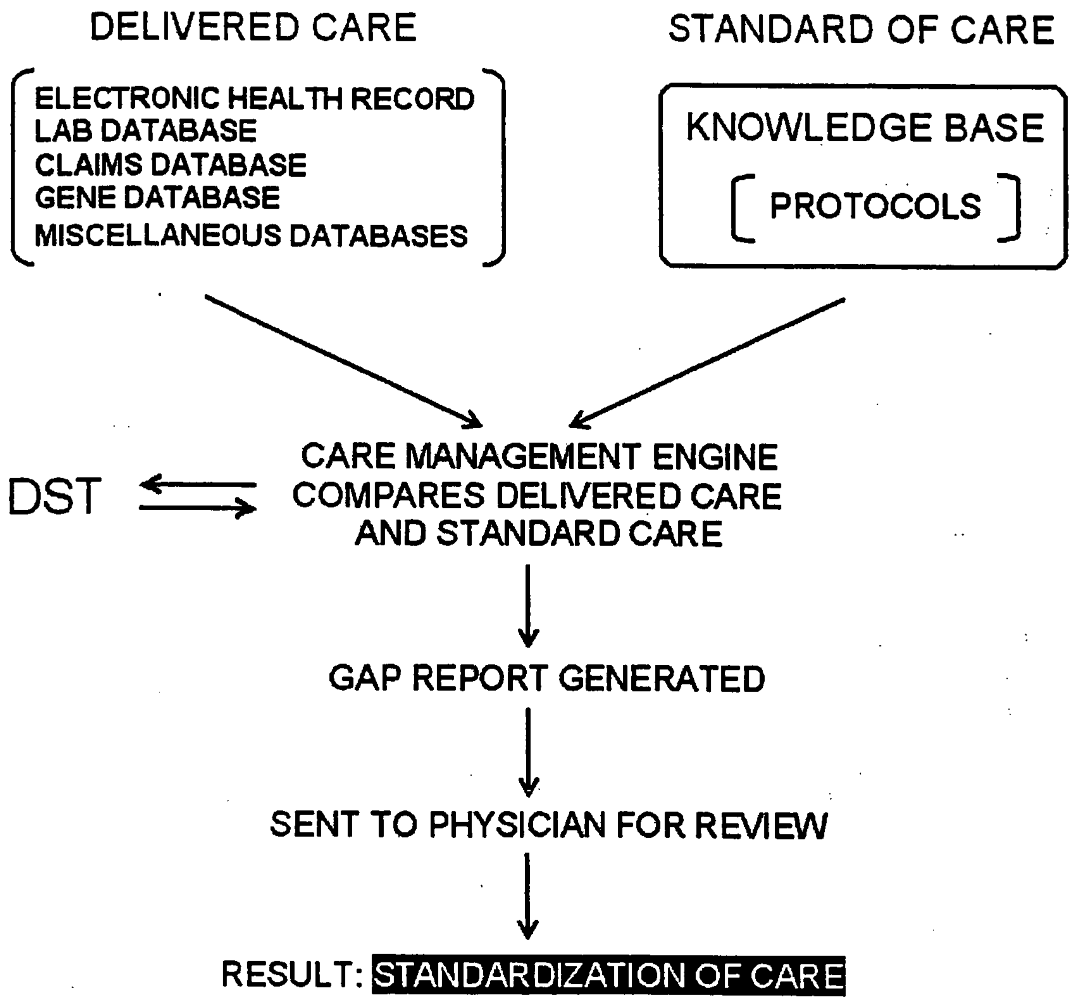


System Architecture, from the viewpoint of Feedback Engine

a. Dialogue Engine- Dialogue Engine maintains ongoing patient interaction that is individualized to the patient. It sends dialogues (content) to the patient for display on the communication device. Dialogues include medical advice to the patient, educational materials, and queries to a patient regarding his/her medical condition. Dialogues can also be script programs instructing the Biometric Device to collect physiological measurements of the patient. Dialogues are generated using Information and Knowledge Base. Dialogues Engine interfaces with the Rendering Engine in order to customize the dialogues to the specific type of communication and biometric devices used by the patient. Replies to dialogues, and measurements from Biometric Devices are fed back into the Information Base.

b. Care Management Engine The individual patient data resulting from the monitoring and management plan will be fed back into the Information Base, where it becomes a part of the patient record that is used in subsequent iterations of the Information and Knowledge Processing System to generate an increasingly individualized care plan with as the knowledge base grows and increases in its precision. This will allow the patient care plan to attain a greater degree of patient specificity and individualization with the passage of time, as the system has a better perspective of a patient's specific needs. As the research and development in this project refines the methodology and semantic network for sharing medical

knowledge, the feedback loop will be enhanced to enable a transition from personalized 'prepackaged programs' to truly patient specific 'individualized programs'. Care Management Engine may also interface with DSTs in order to provide gap reports, as shown in the figure below.



c. <u>Research Engine</u>: The data aggregated from the original patient profile in combination with the longitudinal data created from the patient monitoring and management plan will be aggregated across the entire population of patients in the system. Such data will be blinded and no individually identifiable characteristics will be retained. The research engine tool set will enable a researcher to perform a query on a patient population and to identify subgroups of that population with different characteristics. With these clusters, the researcher will then be able to search for any other variable with meaningful correlation to the respective clusters. Examples of searches that will be performed include identifying subgroups of patients who respond differently to a pharmaceutical treatment regimen, and then to identify other characteristics that correlate with the sub grouping in outcomes. Examples include patient behavior, environmental variables, and gene variation. The goal is to enable academic research to identify characteristics that predict disease progression and complications so that

standards of care can be further individualized and the knowledge base will be continuously enhanced.

One particularly interesting use of the research engine is specifically to correlate subgroups of patients based on treatment response and disease outcomes (phenotypic variables) to genetic variation. Many chronic diseases such as diabetes, hypertension, cardiovascular disease, obesity, and mental health disorders are thought to have a genetic component. The current effort uncovering single nucleotide polymorphism markers (SNPs), representing the common variations among the DNA of individuals, holds promise of understanding the genetic basis of chronic disease and related drug response (pharmacogenomics). The problem, however, remains that complex disease may have multiple etiologies, and the interaction of multiple genes with behavioral and environmental factors may underlie chronic disease occurrence and progression. This project will assess the feasibility of conducting genetic epidemiological research using longitudinal patient data on phenotype and environment variables collected through patient monitoring and management plan in a population of patients. The goal will be to: (1) develop a program that monitors phenotype and environmental variables for a specific set of diseases; (2) work with a clinical site to collect daily data from patients; (3) quantify phenotype and environment variability in sub-populations stratified by genetic factors; (4) develop linkages to life sciences projects capable of collecting and analyzing serum sample for genotyping; and (5) develop statistically appropriate design/analysis methods for assessing phenotype-genotype-environment associations.

III. Project Aims:

<u>RESEARCH AND DEVELOPMENT PHASE (0-24th month)</u>

- To develop a multi-dimensional model of disease and representative form of a patient's disease state; and to link the ongoing longitudinal monitoring to model, in terms of risk expression and aspects of care. Further, to structurally relate Knowledge Base and Information Base to the multi-dimensional model, which will enable the other objectives of the system.
- To create the required content including patient queries and dialogues, and to categorize it by key aspects of patient care, in order to ensure a holistic approach towards patient care.
- To develop a Dialogue Engine that will individualize medical management to the patient, and will allow the patient to be ubiquitously monitored, between clinical encounters, and in a manner that fits into his/her lifestyle. To link Dialogue Engine with Rendering Engine to ensure content presentation on an entire range of devices, and greater patient connectivity.

- To develop a Care Management Engine that automates content assignment on the basis of Information Base of a patient and Knowledge Base of the disease.
- To develop a Research Engine that permits researchers to identify subgroups and correlates of individuals with unique variables in their profile that set apart their condition from the rest of the individuals; and to test hypotheses on this database of individuals.
- To link remote care systems to Decision Support Tools, that will enable a paradigm shift from current manual processes and methods of risk stratification to automated individualized care; which will additionally optimize caregiver time, and enhance productivity.
- To develop an open interoperability standard for all components of the system, including Knowledge base, Information base, Decision Support Tools (DST) and Rendering Engine.
- To test the interoperability between Feedback Engine, Knowledge Base, Information Base, DST and Rendering Engine, and its compatibility other Integrated Project components, with currently used systems (including communication systems), and with external data systems, including legacy database systems.

<u>VALIDATION PHASE (25- 48th month)</u>

- To apply the system in the management of chronic health diseases in a demonstration project in multiple centers across Europe, in a randomized control study
- To compare outcomes of disease managed by the system vis-à-vis that managed by present means, and aggregate data analysis for global impact. Outcomes analyses include health outcomes, cost-savings.
- To measure the impact the remote health management system has on certain key measures including: patient acceptability, satisfaction, utilization, clinical impact, medication compliance, quality of life, cost of care
- To conduct site specific data analysis by country, disease, and care model.
- To assess the feasibility of conducting genetic epidemiological research using longitudinal patient data on phenotype and environment variables collected through patient monitoring and management plan in a population of patients.

IV. State of the Art:

Health Buddy and the iCare Desktop web service from Health Hero Network is a chronic care management solution that enables care providers to remotely monitor patients and detect problems early, while supporting daily patient education and treatment compliance. The Health Buddy appliance was introduced 1999 in the US and in 2003 in Europe. Over thirty care provider sites are currently monitoring 2,500 chronic patients everyday, and over two million patient surveys have been taken to date. Sites where the disease management solution has been implemented include Veterans Health Affairs, Mercy Health System and Kaiser Permanente in the United States. Implementation is in process at Université Louis Pasteur (ULP), Strasbourg, France as a part of post-transplant care management program, and 150 patients are expected to be enrolled in the program in 2003.Additional implementations in process in Europe through agreements with Abbey Healthcare Ltd (Ireland) and Sananet B.V. (Netherlands).

Currently available programs include heart failure, coronary artery disease, diabetes, asthma, COPD, hypertension, and mental health, in addition to custom programs authored by care providers such as for post-transplant care and obesity.

Current Technology

The Technology

The Health Hero platform consists of a series of web-based applications anchored by the Health Hero® iCare Desktop™ and a series of patient interfaces. The primary patient interface, the Health Hero Health Buddy®, is an easy-to-use information appliance placed in the patient's home. Health Hero provides other patient interfaces such as Health Buddy Web, for internet-savvy patients, and are in development stages for patient interfaces based on mobile technologies and interactive television. The web applications and patient interfaces combine to form a secure infrastructure that links providers to their at-home patients while supporting a flexible, cost effective means for daily monitoring.

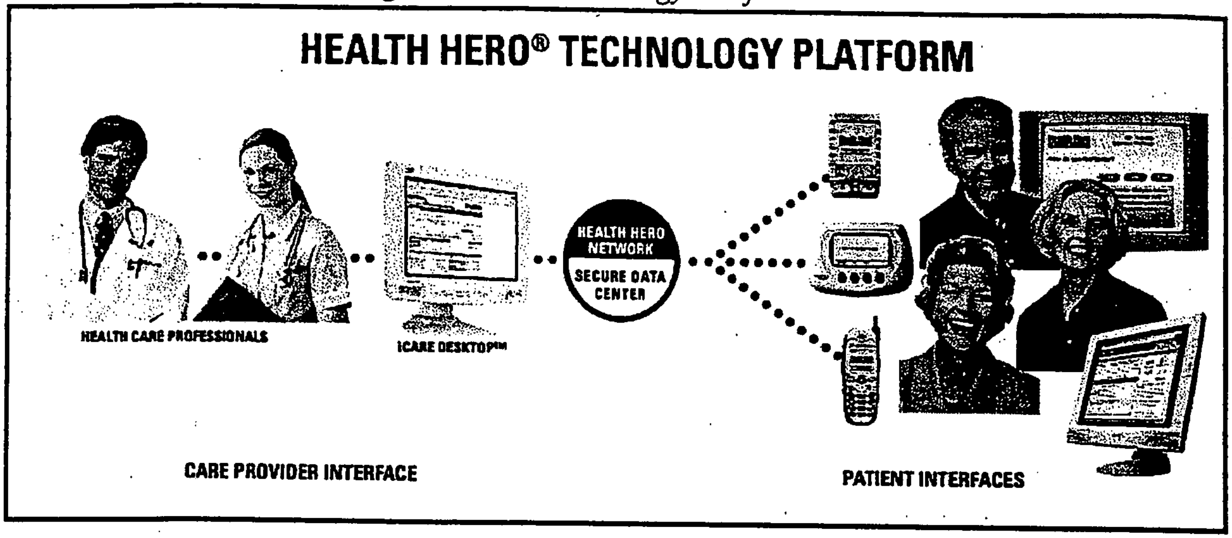


Figure 1: The Technology Platform

Health Hero iCare Desktop

The Health Hero iCare Desktop application provides secure access to a series of web-based tools specifically designed for the patient management and workflow needs of a care provider. The iCare Desktop's capabilities include analysis of patient responses and alerts, review of patient trend data, and production of patient reports. The key feature of the iCare Desktop experience is that it enables care providers to quickly review the status of a large population of patients, which is also what differentiates it from other standard clinical information systems. The review process makes it possible to identify the patients in need of attention or follow-up based on a set of subjective and objective data points giving a total view of the patient's daily health status.

A care provider uses the iCare Desktop to view patient responses and identify responses within a patient population that are stratified as high, medium or low risk in the categories of symptoms, behaviors, and knowledge. This information is used to quickly assess which patients need an intervention on any given day. Care algorithms, Standard Operating Procedures (SOPs) and/or standing orders from the patient's physician guide the intervention. The Health Hero platform collects data that allows care providers to make clinical decisions based on longitudinal data, rather than a single telephone call or data point.

The efficiencies of the Health Hero Platform are realized through the improved data collection capabilities of the Health Buddy appliance and through the workflow features of the iCare Desktop. Disease management programs with care managers using the Health Hero Platform have more than double the number of patients previously managed using a manual approach to disease management.

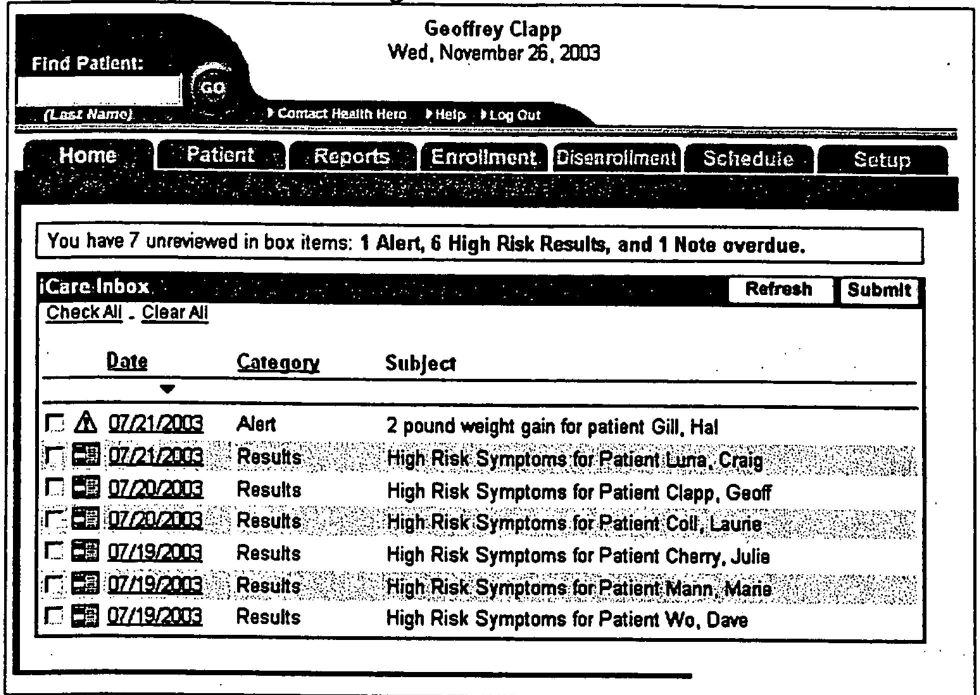
Two specific features that greatly enhance workflow are the Inbox and the Patient Work List. These features provide two different views of patient results, allowing a care provider to deal with events as they happen using the Inbox, or in a more detailed manner withthe Work List.

The Inbox feature of the iCare Desktop collects alerts, high risk and medium risk events in an interface similar to email software. As events are uploaded to the platform, the Inbox automatically creates a "to-do" list of critical tasks for each care provider's

patient population. The items are classified by the standards of care and risk levels stipulated by the patient's care providers .

The care provider is presented with a category and a subject for each Inbox event, describing the results. A typical care provider workflow would consist of scanning the Inbox for results, and either clicking on the date to review the detailed results data, or using the check box to mark that the patient results were reviewed.

Figure 2: The Inbox

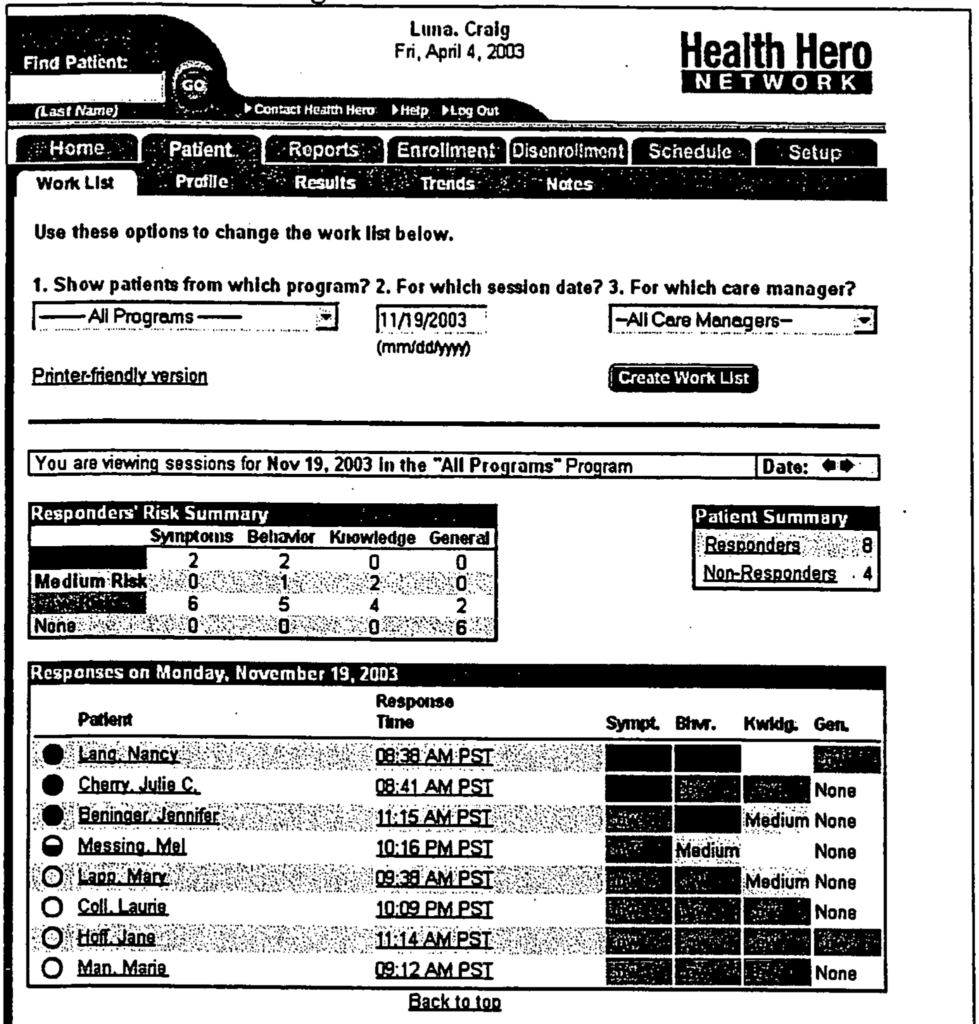


Whereas the Inbox collects a subset of patient results in a to-do list fashion, independent of the date and time, the Patient Work List is designed for review of a population in 24-hour time periods. This view provides the ability to quickly review the health of a population and determine which patients still require further assessment.

The Patient Work List provides options for how the patient results are reviewed. A care provider is able to adjust both the time period of results and the disease programs of patients to displayed.. Supervisors and other iCare Desktop users with the correct permissions can also examine the Patient Work Lists of other care providers for quality control and "out of office" coverage.

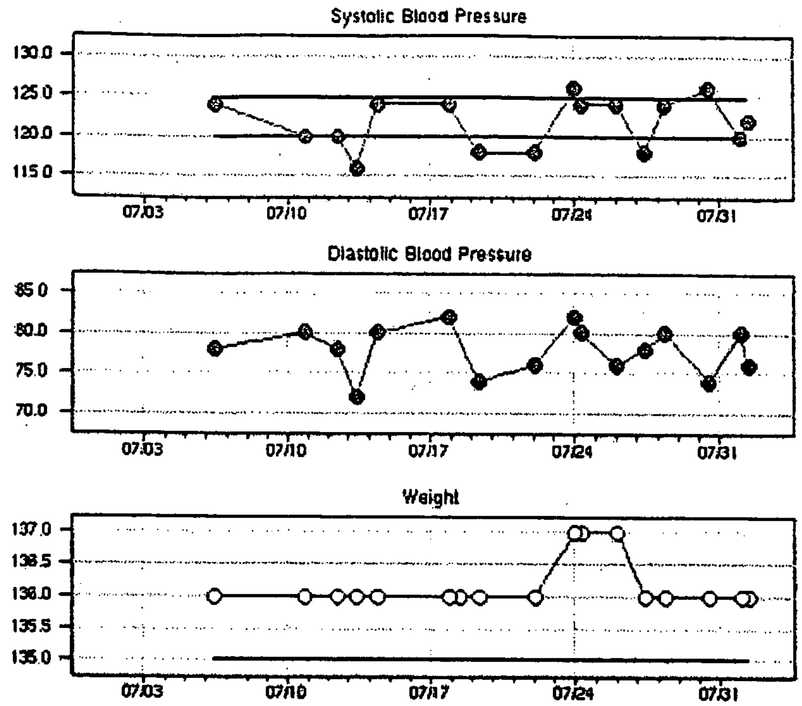
A common question asked by those responsible for the management of a large population of chronically ill patients is, "How do I know I served all the patients who needed care under my SOPs?" The Patient Work List addresses this problem in real-time through the use of a graphical indicator to display the review status of each result. As shown in Figure 3, each row of the Patient Work List includes a circular review indicator. A full circle indicates that the results have been reviewed by the care provider currently looking at the Work List. A half-filled circle indicates that another member of the care team reviewed the result. An empty circle indicates that the result has not been reviewed. This "at-a-glance" interface allows care providers to quickly confirm that an SOP has been followed when appropriate. Full audit logs of the review and disclosure of patient results, including the reviewer name, time and date of review, and method of review are logged and maintained by the Health Hero platform.

Figure 3: The Patient Work List



Care providers have access to patient data collected over time through the trend chart pages, which are graphical representations of the patient data. Analysis aids, such as baseline weights and target goals, can be displayed on the trend charts to provide guidelines for review.

Figure 4: iCare Trend Charts



Teams of care professionals provide the highest quality patient care and all members of the care team must be able to access clinical information for each patient in the manner that is the least disruptive to their existing workflow. The iCare Desktop provides robust reporting tools that facilitate the faxing, emailing, and printing of reports for review outside of the iCare Desktop workflow.

For those members of the care team who choose to use the web-based tools for patient management, the iCare Desktop is designed with role-based permissions, so each individual contributor to the patient's care is able only to interact with the specific patient data that is required to complete their professional function.

Providers access the iCare Desktop from a personal computer with an Internet connection. The iCare Desktop requires no installation of software or hardware, and little-to-no staff support from provider Information Technology (IT) groups. System maintenance, backup, and security is managed by Health Hero Network and it's networking partners.

<u>Health Buddy® Appliance</u>

The Health Buddy appliance, shown in Figure 5, serves as the primary patient interface for secure communication between patients and the network. The Health Buddy was designed as an easy-to-use communication appliance for placement in the patient's home, and has gone through significant commercial validation as a welcome in-home healthcare tool.

The ease of use begins with the Health Buddy installation process, which is most often conducted by the patient with no assistance. The Health Buddy requires a standard telephone outlet and standard power outlet, and requires no additional telephone lines, software, or computer experience. When power is applied, the Health Buddy presents the

patient with an interactive Health Buddy tutorial, and then within one hour of taking the tutorial, the patient receives their first Health Buddy survey.

The Health Buddy provides the patient with at least one survey per day. The surveys are designed to enable patients to easily respond to a range of questions, that relate to important aspects of care for their specific condition. Once the patient answers the questions in the survey, the Health Buddy stores and transmits the information back to the care providers, who will review the data using the iCare Desktop. Although the standard model of care for patients uses a once-per-day survey transmission mode, the transmission of results can be customized to upload patient data at any desired frequency, including in response to a particular patient result.

Figure 5: The Health Buddy

The Health Buddy is intended to gather quantitative and qualitative patient information through a simple question, answer and education session. In some cases, it is important to augment quantitative and self-reported qualitative data with information collected directly from medical devices. The Health Buddy appliance, through the Buddylink™ feature, allows the collection of data from medical devices, such as blood glucose meters, weight scales, and blood pressure cuffs. The objective data is collected during the survey process so that the patient still benefits from the education, behavior modification, and personalized responses.

The benefits of employing the Health Buddy and the iCare Desktop web service in disease management have been validated in articles published in several peer-reviewed journals. Briefly, the Health Hero Disease Management Programs have shown clear benefits over other programs, in terms of-

<u>Cost Benefits</u>: Health Buddy reduces hospital admissions and costs by detecting problems before they become a crisis. A recent study at the Veterans Health Affairs reported a 60% reduction in hospital bed days of care in a one year trial with 791 CHF, COPD, diabetes, and hypertension patients in a chronic care program in which most patients were monitored daily using Health Buddy. Similar cost savings were reported in Medicare HMO patients. (Meyer et al, Disease Management 2002; 5: 87-94. Vacarro et al, Disease Management 2001; 4(3): 1-10.)

Access to Care: Health Buddy increases access to care by expanding the capacity of care providers to monitor patients using existing resources. Through daily communication, patients are able to access timely care before conditions become a crisis. At Mercy Health System, a part-time nurse provides daily monitoring for 425 heart failure, diabetes, and hypertension patients. With telephone-based monitoring only, a full-time nurse could provide weekly monitoring to less than 100 patients. The efficiency achieved through Health Buddy allowed for coverage of uninsured patients who otherwise would have received no care at all. (Cherry et al, Diabetes Technology & Therapeutics; 4(6): 793-791.)

Quality of Care: Health Buddy improves quality of care by providing timely, relevant, and actionable information to healthcare providers so that care can be coordinated in a quality assured process. Care providers are able to detect complications before they become acute and result in hospital admissions, providing quality care that reduces painful and costly complications by maintaining patients in a healthier state. Health Buddy also improves patient outcomes by improving treatment compliance through educating, motivating and monitoring patients daily. (Cherry et al, Lippincott's Case Management 2000: 5(5): 191-198. Guendelman et al, Archives of Pediatric and Adolescent Medicine 2002: 156: 114-120.)

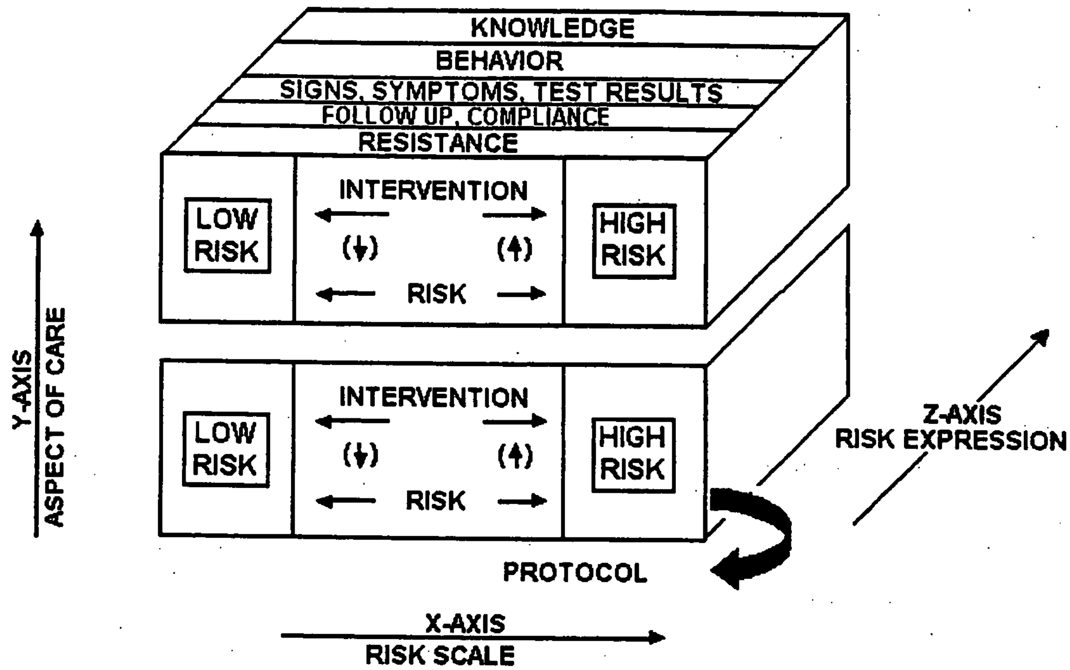
V. Scope for Innovation-

	State of the Art	Scope for Innovation
Patient Dialogue Engine	Pre-packaged, mass customized programs	Automated individualization of programs
	Content libraries	Content generated by knowledge base rules applied to information base
	Health Buddy	Interface to Rendering Engine for any device
Care Management Engine	Risk stratification	Intelligent risk tuning and link to DST
	Organizational workflow and efficiency tools	Organizational optimization
	Manual feedback process	Automated feedback loop
Research Engine	Data Export to SAS	Identify subgroups and correlations
		Test hypotheses on living database

Table: The contribution of Feedback Engine in terms of innovation

VI. Multi-Dimensional Model of Disease

The 3-Dimensional Model of Disease-



A 3-dimensional model of disease.

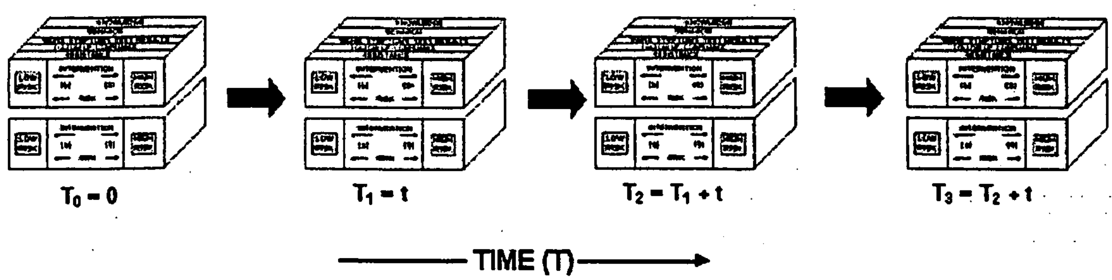
The above diagram illustrates a three dimensional model of disease. In this model, a patient's health *at a point in time is* determined on a relative risk scale. The Y-axis contains slabs, each relating to a specific aspect of care. For instance, in a multi-system disease like Diabetes, one slab relates to blood glucose control, another to the cardiovascular system, still others to foot care, the neurological, renal and ophthalmic systems. Given the complex multiple interactions between different aspects of care, there may be occasional overlap between different slabs. For instance, glucose control, when applied in the long-term sense, is related to the cardiovascular, renal and most other systems. In such cases, each factor of interest is represented separately and independently on the Y-axis.

Each aspect of care in the individual patient is further modulated by a patient's knowledge of disease (in that aspect of care), patient behavior, signs, symptoms, test results, and general resistance to medical advice. Each such aspect of risk expression is represented in the model on the Z-axis. A specific aspect of care (Y) for a specific expression of risk (Z) is termed a 'health context'. The X-axis relates to the relative level of risk exhibited by an individual patient for each health context. Lower x values of a patient indicate a better state of health.

For example, in case of blood glucose control in diabetes, the actual behavior of the patient, and disease outcomes are a function of the

1. Patient's knowledge- a patient with a greater knowledge (lower risk) of the long-term complications of diabetes, and its relationship to blood glucose control is more likely to be compliant with the diabetic diet and regimen (better outcome).
2. Behavior- Humans exhibit varying behaviors regardless of the level of knowledge of their disease condition. Some individuals are more health conscious (lower risk) than the others.
3. Signs, Symptoms, and test results-. A patient whose blood glucose values are consistently within the normal range (lower risk) gets the requisite positive feedback, encouragement, and impetus to further adhere to the prescribed medical regimen. Conversely, patients who develops complications of medication, such as nausea, vomiting or hypoglycemic attacks are at a greater risk of being non-compliant with medical advise.
4. Follow-up, compliance, and Resistance- On continued follow-up, one or more of the above factors may change. For instance, as a patient's knowledge of his/her disease condition increases, he/she may be more inclined to be compliant with the medical regimen. Resistance is defined as the tendency of patients to resist medical care and the changes it entails with regard to one's lifestyle and habits. In the context of the disease model, resistance is additionally related to a patient's perception of the value of medical regimens.

The Fourth Dimension: Time- The three dimensional model is 'static', in that it doesn't describe the changes that take place in the patient's disease state with time, nor is it descriptive about the effects of various interventions and medical therapies on the Information Base. To this end, the fourth dimension of time is added to the three-dimensional model. The aim of disease management is to achieve the lowest overall risk in a group of patients.



It permits outcomes analysis to be performed. Additionally, it allows one to study (and test) effects of multiple expressions of risk and aspects of care with regard to one another, as a function of time, in a single patient.

<u>Description of System Components in relation to the Multi-Dimensional Model.</u>
Knowledge sources and medical literature typically supply recommendations as to 'standard of care' in the form of care management algorithms. However, these algorithms would need to be interpreted and applied into the system by Decision Support Tools and Care Management Engine. Further, the format and logic would need to be common for all the system sub-components, in order that interfacing is made possible by the use of Application Program Interfaces. Finally, the logic has to be mapped to the multi-

dimensional model of disease. The proposed system architecture, type, nature, and format of data exchange between the system's components will be better understood when explained in reference to standard care management algorithms. One such algorithm, specifically an algorithm relating to the management of patients with congestive heart failure by Care Managers is given in the table below-

TITLE:	CONGESTIVE HEART FAILURE SURVEILLANCE DIURETIC ALGORITHM
POLICY:	1. Function: To outline the nursing management of patients who are referred by their physician to Health Buddy Congestive Heart Failure Program. Registered nurses independently titrate the patient's regularly prescribed diuretics and potassium based on the patient's symptoms and weight gain using an approved algorithm. Circumstances under which the RN may perform this function: Registered nurses who work in Health Buddy Congestive Heart Failure Disease Management Program may initiate this standardized procedure when directed by the patient's physician. Patient contraindications to use of this standardized procedure include pulmonary edema, new or refractory chest pain, new or sustained arrhythmia, syncope.
PROTOCOL:	1. Definition – The Health Buddy Congestive Heart Failure Disease Management Program is an outpatient-based approach to managing chronic CHF patients, where Registered Nurses provide education, support, and clinical follow-up to patients with congestive heart failure under the direction of a Physician. 2. Assessment – Assess patient for signs and symptoms of worsening congestive heart failure • Breathlessness, paroxysmal nocturnal dyspnea, orthopnea, dyspnea at rest • Weight gain • Edema • Compliance with medication regime • Compliance with dietary restriction

PROCEDURAL STEPS	KEY POINTS
1. Once a change in status has been indicated, interview patient via telephone to verify the patient's status. 2. Interview patient to determine subjective complaints of SOB, fatigue, and other signs & symptoms of CHF. 3. Based on the patients subjective symptoms and current weight, implement the following.	Total daily doses of diuretics should not exceed the following limits unless approved by physician: Lasix 240 mg, Bumex 10 mg, Metolazone 5 mg, Demadex 240 mg.

Patient's Symptoms	*Weight Gain in Pounds*	*Treatment Category*	*Treatment Legend*
No new symptoms	1-2	Restrict salt	1= Extra dose of the patient's regularly prescribed diuretic and potassium now*. 2 = Extra dose of the patient's regularly prescribed diuretic and potassium now, then an extra daily dose for 3 days.* Daily phone calls from Health Buddy nurse. Obtain renal panel within 48 hours if current creatinine >1.8. 3 = Double dose of the patient's regularly prescribed diuretic and potassium now, then an extra daily dose for 3 days.* Health Buddy nurse will notify patient's primary physician. Obtain renal panel within 48 hours if
	3-4	1	
	>4	2	
New or worsening paroxysmal nocturnal dyspnea	1-2	1	
	3-4	3	
	>4	3	
Orthopnea	1-2	2	
	3-4	3	
	>4	3	
Shortness of breath when seated	1-2	2	

	3-4	3	current creatinine >1.8. 4 = Double dose of the patient's regularly prescribed diuretic and potassium now and again in 4 hours.* Health Buddy nurse will notify patient's primary physician; office visit scheduled. Obtain renal panel (if current creatinine >1,8) and Mg++ within 48 hours. 5 = Refer to emergency department. Health Buddy nurse will notify physician and appropriate emergency department.
	>4	4	
Pulmonary edema refractory to treatment category 4, chest pain (new or refractory to nitro), arrhythmia (new or sustained), syncope		5	
4. To manage the patient who loses weight below their pre-determined dry weight: 2-3 pound weight loss-- halve diuretic for one day; if recurrent, reduce to half dose every other day.* 4-6 pound weight loss – reduce diuretic to half dose daily, obtain renal panel*, and notify physician. 7 or more pounds – hold diuretics, obtain renal panel*, and notify physician.			*Essential to reduce potassium supplements an equivalent amount.
5. To manage the patient with excessively rapid weight loss: 3-5 pounds in 24 hours** -- confirm appropriate potassium replacement. Weight loss of more than 5 pounds in 24 hours** -- confirm appropriate potassium replacement, obtain renal panel, and notify physician.			** If weight loss continues longer than 24 hours, obtain renal panel and notify physician.
7. Follow-up phone calls from Health Buddy nurses are required for treatment categories 2, 3, 4, and 5 and for all patients with weight loss below dry weight and excessively rapid weight loss within 72 hours of initiating the treatment change.			The primary physician must be consulted if the patient meets criteria for emergency department referral, weight loss below dry weight of 4 or more pounds, and excessively rapid weight loss of more than 5 pounds in 24 hours.

Table: A health context management algorithm

Knowledge Base: Knowledge Base, the summation of medical knowledge and concepts is organized by location pointers, expressions that define the location of any aspect of disease on the multi-dimensional model, and protocols, which are logical expressions that define the relationships between the health contexts, and the actions that need to be taken for possible combination of factors within the health context. Within the multi-dimensional model of disease, location pointers are represented on the X, Y- and Z-axis. Every possible piece of information that is collected by the system is mapped on to the 3-dimensional model.

In the above example,

DIRECTIONAL POINTER: CHF SURVEILLANCE				
DISEASE:	CONGESTIVE HEART FAILURE			
ASPECT OF CARE:	DIURETIC MANAGEMENT			
KNOWLEDGE:	OF ORTHOPNEA	YES	NO	

	OF PAROXYSMAL NOCTURNAL DYSPNEA	YES	NO	
	OF NECESSITY TO RESTRICT SALT	YES	NO	
BEHAVIOR:	EXERCISING REGULARLY	YES	NO	OCCASIONALLY
	RESPONDS TO HEALTH BUDDY	YES	NO	OCCASIONALLY
	RESPONDS TO PHONE CALLS	YES	NO	OCCASIONALLY
SIGNS:				
SYMPTOMS:		NO NEW SYMPTOMS	NEW OR WORSENING PND	ORTHOPNEA
TEST RESULTS:	WEIGHT GAIN	1-2 LB	3-4 LB	>4 LB
	CREATININE	<VALUE>		
	WEIGHT	<VALUE>		
	K+ LEVEL	<VALUE>		
COMPLIANCE:	COMPLIANCE WITH MEDICATION	GOOD	MODERATE	POOR
	COMPLIANCE WITH DIET	GOOD	MODERATE	POOR
FOLLOW UP:				

Thus, Knowledge Base defines the location of the particular attribute on the model. It is common to all patients with a single disease. Further, the 'risk-states' that are given to a particular variable is defined at the time of creation of the model. For example, in the health context of Behavior (Responds to phone calls), a value of 'Yes' will lie towards the low risk end of the X-axis, while, a value of 'No' will lie towards the high risk end. For continuous variables, for example, the results of a laboratory test, or Creatinine values, the value of a health context is represented as such, on a scale. In case where a low value is medically significant, such as a low serum potassium value, it is represented by two contexts, one for hypokalemia (low potassium) and another for hyperkalemia (high potassium values). On the contrary, if low values of a measurement have no medical significance, for example Creatinine value, then it is represented by a single context.

In order to automate patient care, and to achieve the other objectives of the system, it is necessary to incorporate into the system, the logic that will enable it to decide on a course of action to be taken, or a treatment plan, which are the Protocols. Protocols tell the system the action that needs to be taken for any of a combination of unique variables in

the Information Base. Protocols are the 'threads' or connections that link the discrete data components that ultimately forms the Information Base.
In the above context,

PROTOCOL: DIURETIC PRESCRIPTION
IF SYMPTOMS= 'NO NEW SYMPTOMS' AND WEIGHT GAIN = '1-2' THEN ACTION: RESTRICT SALT
IF SYMPTOMS= 'NO NEW SYMPTOMS' AND WEIGHT GAIN = '3-4' THEN ACTION1: INCREASE_DOSE_DIURETIC THEN ACTION2: GIVE PATIENT POTASSIUM
IF SYMPTOMS= 'NO NEW SYMPTOMS' AND WEIGHT GAIN = '>4' THEN ACTION1: INCREASE_DOSE_DIURETIC THEN ACTION2: GIVE PATIENT POTASSIUM FOR 3 DAYS THEN ACTION3: ALERT CARE MANAGER: TO PHONE PATIENT THEN ACTION4: OBTAIN RENAL PANEL

<u>Information Base-</u> This is individual to a patient, and is created in response to the data (responses to queries), measurements of the patient, and external data sources. In the 3 dimensional model of disease, a new 3-dimensional model is created for each new piece of information. In general, the information base provides a health profile of the individual at that point of time, and is sufficient for deciding the care management, when used in reference to Knowledge Base. The table below depicts the Information Base of a particular patient at a point in time.

PATIENT NAME: SCOTT, JANE				
DISEASE:	CONGESTIVE HEART FAILURE			
DATE, TIME	9 APRIL 2003, 1400 HRS, GMT			
KNOWLEDGE:	OF ORTHOPNEA		NO	
	OF PAROXYSMAL NOCTURNAL DYSPNEA	YES		
	OF NECESSITY TO RESTRICT SALT	YES		
BEHAVIOR:	EXERCISING REGULARLY			OCCASIONALLY
	RESPONDS TO HEALTH BUDDY	YES		
	RESPONDS TO PHONE CALLS			OCCASIONALLY
SYMPTOMS:		NO NEW SYMPTOMS	NEW OR WORSENING	ORTHOPNEA

			PND	
TEST RESULTS:	WEIGHT GAIN		3-4 LB	
	CREATININE	1.7		
	WEIGHT	149 LB		
	K+ LEVEL	4.4		
COMPLIANCE:	COMPLIANCE WITH MEDICATION	GOOD		
	COMPLIANCE WITH DIET		MODERATE	

However, in some cases, current Information Base alone is insufficient in deciding the course of management of the patient. Previous or baseline values are required for comparison. This is especially the case where the laboratory values are used. For example, in this patient with Congestive Heart Failure, a weight of 65 kg, has no meaning in itself, unless it is compared with the patient's previous weight. A weight gain could be the first sign of fluid accumulation and impending heart failure.

Serial follow-up of Information Base has immense Research utility, for example in outcomes analysis, and in correlating the effects of a new drug or intervention on an entire range of patient variables.

<u>Decision Support Tools</u>- Decision Support Tools determine the extent to which provided care is consistent with the consensus standard of care. For example, in Diabetes, knowledge base protocols will require that the patient has a HbA1c test every three months. The following protocol logical expression is applied to determine if the standard of care has been followed.

PROTOCOL
IF [DATE(TODAY)] - [DATE(HBA1C-TEST)] ≥ 90, THEN
DOACTION: INFORM CARE_MANAGER(PATIENT)

The following protocol 'tells' the Decision Support Tools the effects that a particular intervention has on the risk factor levels of different health contexts. On increasing the daily injected insulin dose, the risk of developing hypoglycemic episodes is raised significantly, also there is a risk of weight gain and an increased cost of medication to the provider. Finally, the biometric device is scheduled to receive three blood glucose samples for a week.

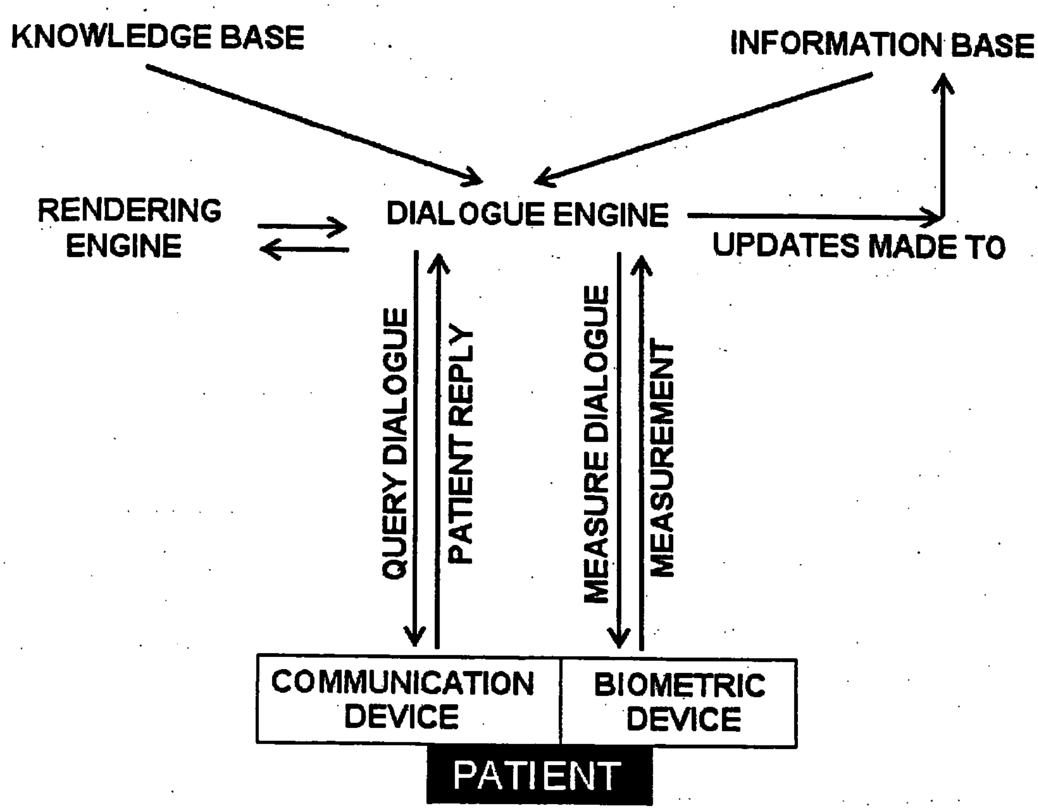
IF INTERVENTION(INCREASE_INSULIN_DOSE)= 'TRUE'
THEN RISK(HYPOGLYCEMIC_EPISODE) = RISK + (VAR1)
ALSOTHEN RISK(WEIGHT_GAIN_NEAR_TERM)= RISK + (VAR2)
ALSOTHEN (MEDICATION_COST) = (MEDICATION_COST)+ (VAR3)
ALSOTHEN DO (TEST_GLUCOSE_VALUE)= 3TIMES/DAY * 1 WEEK

In deciding the course of management of the patient's condition, DSTs reference the Information Base and the Knowledge Base.

VII. Feedback Loops-

The Feedback Engine will enable a regular and ongoing interaction between the patient and the care manager, physician and researcher, outside of the clinical encounter. There will be three main types of feedback loops- the Information Feedback Loop, the DST Feedback Loop, and the Research Feedback Loop.

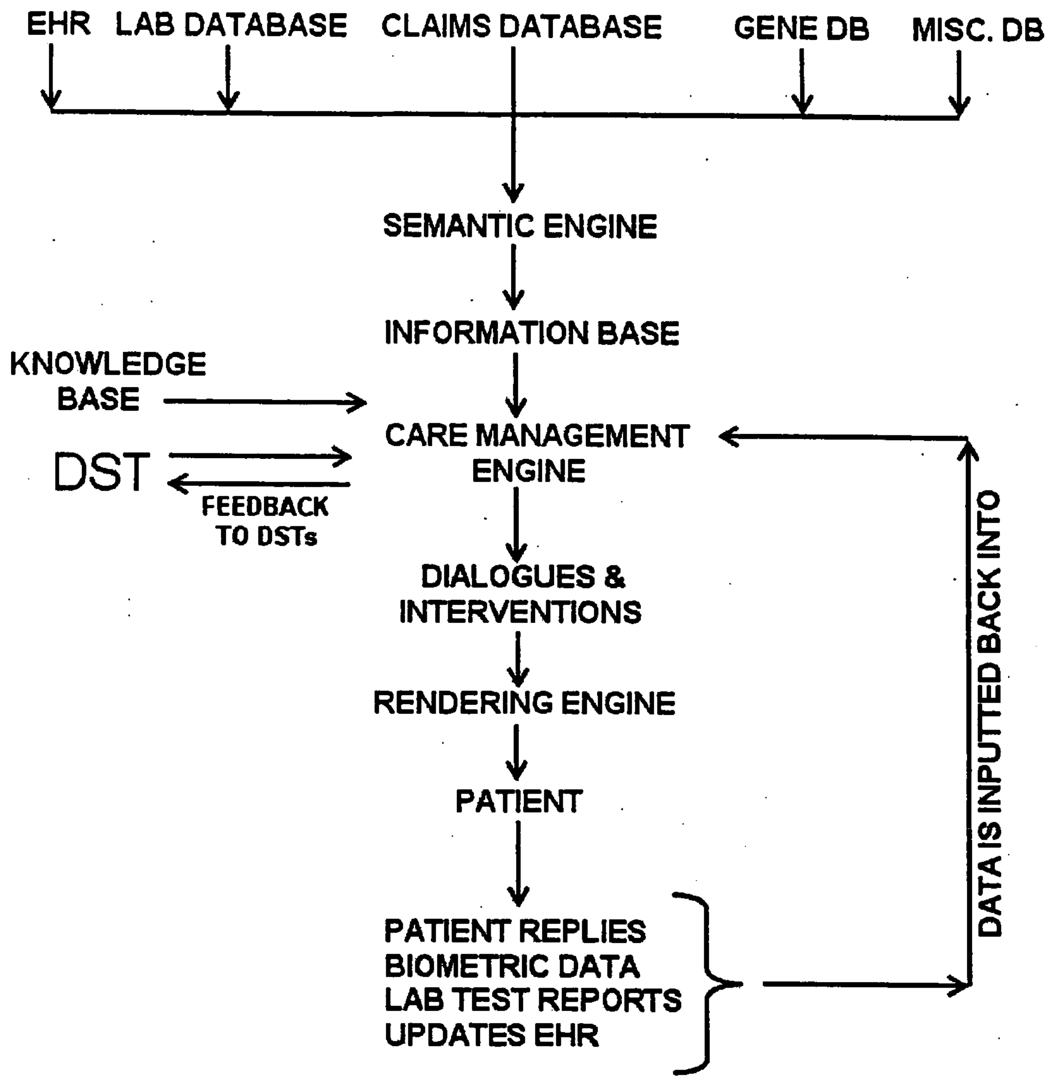
The Information Feedback Loop- The Information Feedback Loop provides feedback to the Information Base. It is the feedback loop from the perspective of a patient, enabling individualized communication, and ubiquitous monitoring of a patient. Updates to the patient Information Base are made automatically, and in real time, thus allowing for reduced latency from the provision of information to action taken. Dialogues are not only customized to comprehensive and updated information, but also are rendered for output in a variety of formats.



INFORMATION FEEDBACK LOOP

In the first step, Dialogue Engine links to Knowledge Base and Information Base in order to create and select dialogues that are most suited to the patient's Knowledge Base and Information Base. In the next step, Dialogue Engine interfaces with Rendering Engine to format the dialogues for transmission and uptake by the patient communication device and biometric device. Query Dialogues are sent to the Communication Device, for display to the patient. Additionally, Dialogues are sent to Biometric Device, either directly, or via communication device with commands to collect measurements of physiological variables. Replies of the patient and measurements from biometric devices are re-routed to the Dialogue Engine through the same communication system. The Dialogue Engine further interfaces with Rendering Engine, in order to interpret the signals, and appends the newly collected data to the Information Base. The updated Information Base is in turn used in subsequent iterations of the patient management process.

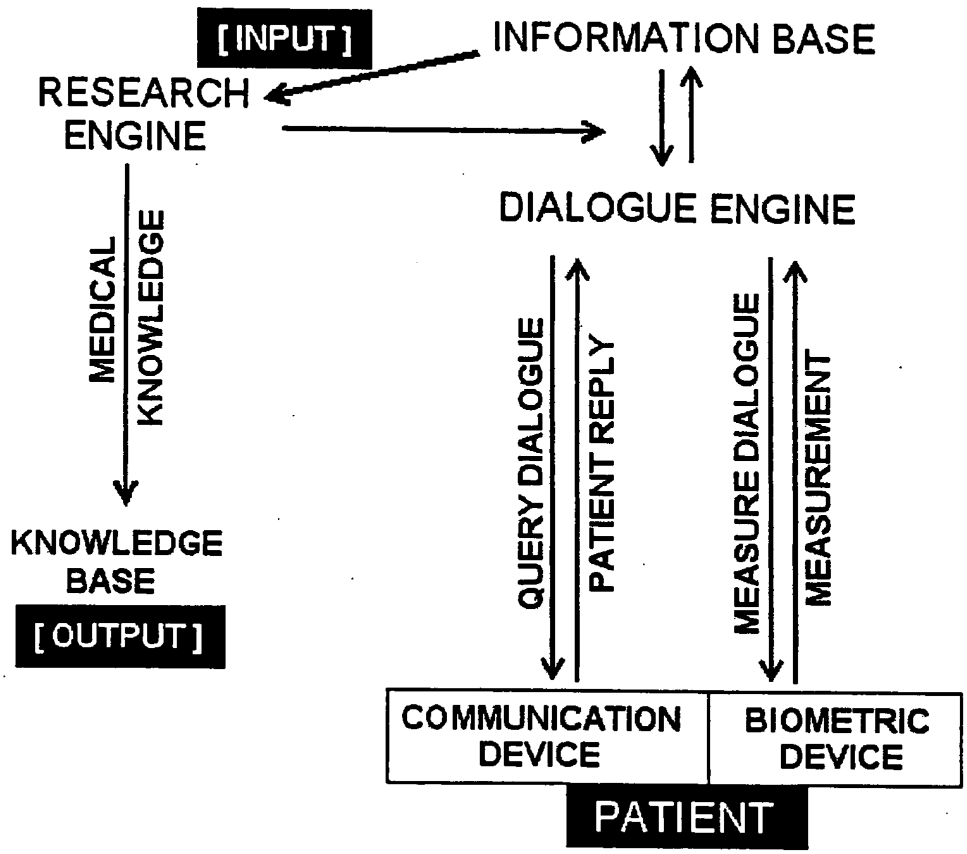
DST Feedback Loop- The DST Feedback loop provides feedback to Decision Support Tools, and its updating in real time, resulting in care that is provided on the basis of patient data that is updated in real time.



DST FEEDBACK LOOP

In the first step, the Care Management Engine interfaces with Information Base, Knowledge Base, and DSTs to create Dialogues and Interventions suited to the patient's disease condition. These dialogues and interventions are rendered to the format of communication by rendering engine. Patient replies to query dialogues, Biometric test results, and updates of Laboratory and EHRs are fed back into the Information Base. The feedback provided from the received data is used to create better Decision Support Tools that enable better automated processing of patient care.

Research Feedback Loop-



RESEARCH FEEDBACK LOOP

Research Feedback Loop is primarily used by a researcher to make new discoveries and to test hypotheses on the system. Information Base is organized in the form of a neural network, thus enabling the Research Engine to scan the data, and to look for correlates in the data, or events that have a greater correlation than can be explained by chance alone. These correlates are forwarded to the Researcher, who will form a hypothesis. In order to test the hypothesis, the Researcher may use Research Engine to interface with Dialogue Engine, and use it to create Dialogues and requests for measurements from Biometric Device. The results of the queries and tests measurements are forwarded to Information Base, and thence to the Researcher. Further statistical analyses may be performed, and associations may be elicited. For example, the researcher may be able to prove the existence of an unknown factor in a chronic disease that causes different people to respond differently to medication. Further correlation with molecular and genetic studies may be done to prove or refute the hypothesis.